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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/783,152

02/20/2004

Rafail Zubok

532/7X2

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01/25/2008

SPINE MP

LERNER, DAVID, et al.

600 SOUTH AVENUE WEST

WESTFIELD, NJ 07090

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

01/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/783,152

Applicant(s)

ZUBOK ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-12 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/2/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/2/07 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that the device has fork shaped extensions that move and are in parallel planes when in open and closed positions was not described in the written disclosure.

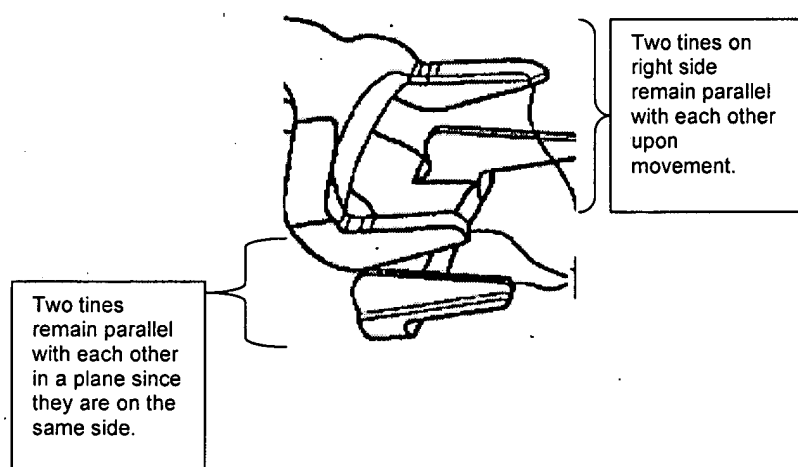
Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-5,8-10,16,18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Aebi et al. (6261296). Fig. 14 shows an instrument **200** having an

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actuation handle **212** with fork-shaped extensions **214** extending from the distal end. It can also be seen there are base portions for the extensions or elongate sections that can be arbitrarily said to extend from the hinge portion of the handle. The base portions can be construed to be U-shaped, form a vertebral stop and have a curved profile. Fig. 5 shows an intervertebral disc to be inserted with upper and lower baseplates that can be positioned between the fork-shaped extensions. One set of tines is longitudinally aligned with the elongate section as seen in Fig. 16. Regarding the limitation that the fork shaped extensions are in parallel planes when in open and closed positions, it can be seen below that on each side there are opposing tines of the opposing fork shaped extensions that have planes perpendicular to the elongate axis of the instrument that remain parallel when open and closing.



It should also be mentioned that Fig. 3 shows two pivot points nearest the distracting end of the instrument. As a result the forked shaped extensions have planes that remain parallel as the distance between them increases during distraction. With respect to claim 18, it can be seen (Fig. 16) that there are longitudinal axes that lie between the

tines and is offset from the longitudinal axis of the actuation handle. The Examiner considers the pivoting point as the intermediate portion from where the fork shaped extensions extend. The base clearly has dimensions or interior sides adapted to grasp an artificial intervertebral disc.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al. '296 in view of Neumann (EP 1219266). Aebi et al. is explained supra. However, Aebi et al. fail to disclose the stop having a ridge oriented perpendicular to the tines' outward surfaces or a notch in the interior surface of the extensions. Neumann teaches (Fig. 11) a fork-shaped extension having a base **26** and a pair of laterally spaced tines perpendicular to the base and slight notches in the interior between the upper and lower tines. It would have been obvious to one of ordinary skill in the art to incorporate a ridge and notch in the extension fork-shaped distraction end as taught by Neumann with the instrument of Aebi et al. such that it provides more stabilization for the instrument to hold the implant and less likely to slip from the instrument.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al. '296 in view of Keller (DE 3023942). Aebi et al. is explained supra. However, Aebi et al. fail to disclose the plying device comprises at least two hinges. Keller teaches (Fig. 6) a plying device having at least two hinges in the intermediate portion and an

actuation handle. It would have been obvious to one of ordinary skill in the art to incorporate multiple hinges as taught by Keller with the instrument of Aebi et al. such that it provides a greater length to deliver the spinal device in the patient.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al. '296 in view of Michelson (6080155). Aebi et al. is explained supra. However, Aebi et al. does not disclose the extensions are detachable. Michelson shows (Fig. 2) detachable prongs from the instrumentation. Michelson also teaches (col. 21, lines 2-4, 15-19) that the detachable extensions enable the surgeon to stabilize the implant and perform any other procedures at the implantation site by not having an elongate instrument extending from the patient. It would have been obvious to one of ordinary skill in the art to utilize a detachable forked extension as taught by Michelson and modify the instrumentation of Aebi et al. such that the tool enables the surgeon to separate the handle from the extensions and thus prevents any inadvertent movement of the implant and allows the surgeon to perform any other necessary surgical measures.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al. '296 in view of Buttner-Janz et al. (5401269). Aebi et al. is explained above. It is noted that Aebi does disclose teeth on the implant, see Figs. 4,5. However, Aebi fails to disclose teeth spaced apart from a centrally disposed dome. Buttner-Janz teaches (Figs. 3,4) a centrally disposed dome between the plates and teeth spaced apart towards the perimeter of the plates and on the exterior surface such that they are apart from the dome. It would have been obvious to one of ordinary skill in the art to

incorporate the teeth as placed on the exterior surface of the plates taught by Buttner-Janz in substitution of the teeth of Aebi et al. implant and incorporate an articulating dome centrally within the plates as taught by Buttner-Janz for the device of Aebi such that it allows the device to permit articulation in a patient not requiring fusion.

Response to Arguments

Applicant's arguments filed 11/2/07 have been fully considered but they are not persuasive. Applicant argues that Aebi's device does not have the fork shaped extensions remain parallel when open and closed. However, the Examiner would like to point out that in one embodiment as illustrated above the tines aligned on each side of the extensions can be considered to remain in a parallel plane with respect to each other. The Examiner also considers Fig. 3 to show extensions that would remain parallel upon movement of the instrument handles. Applicants also argue that the tines are not offset from the handle. However, the Examiner would like to refer Applicants to Fig. 16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (8am-4:30pm).

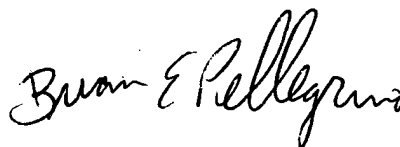
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

A handwritten signature in black ink, reading "Brian E. Pellegrino". The signature is fluid and cursive, with the first name "Brian" and last name "Pellegrino" clearly distinguishable.

BRIAN E. PELLEGRINO
PRIMARY EXAMINER